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510(k) SUMMARY

1. General Information

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Date Prepared: February 1, 2012

2. Device Name

Trade Name: Rotor-Gene® Q MDx
Common Name: Real Time Nucleic Acid Amplification System
Classification Name: Instrumentation for Clinical Multiplex Test Systems, 21 CFR §862.2570

3. Predicate Device

Manufacturer	Product Name	510(k) No.
Abbott Molecular Inc.	Abbott® *m*2000™ System, specifically *m*2000*rt*	K092705

4. Device Description

The Rotor-Gene® Q MDx is a real-time PCR analyzer designed for rapid thermal cycling and real-time detection of PCR assays. The Rotor-Gene Q MDx uses a centrifugal rotary design for thermal cycling where each tube spins in a chamber of moving air, keeping all samples at a uniform temperature. Detection is performed as each tube aligns with the detection optics, where the sample is illuminated and the fluorescent signal is rapidly collected from a single, short optical pathway.

5. Intended Use

The Rotor-Gene Q MDx instrument with Rotor-Gene Q software version 2.1.0 or higher is a real-time nucleic acid amplification and detection system which measures nucleic acid signals from amplified DNA using fluorescent detection.

The Rotor-Gene Q MDx instrument is intended for *in vitro* diagnostic use with FDA cleared or approved nucleic acid tests in clinical laboratories.

6. Technological Comparison

The Rotor-Gene Q MDx instrument and the Abbott *m*2000*rt* instrument are similar in the intended use, assay format, primary operational amplification and detection, and automation. The Rotor-Gene Q MDx and the Abbott *m*2000*rt* instrument differ in the heating method for amplification and amplification reaction volumes. While there are differences, these differences do not raise new types of safety and effectiveness questions.

7. Testing

Analytical and clinical performance of the Rotor-Gene Q MDx instrument is assessed for each assay to be run on this system.

The *artus*® Infl A/B RG RT-PCR assay is being submitted separately, but concurrent with this RGQ instrument submission. Please refer to the *artus*® Infl A/B RG RT-PCR assay 510(k) submission for the *artus*® Infl A/B RG RT-PCR assay analytical and clinical testing which includes the following:

- Limit of Detection,
- Limit of Blank,
- Reactivity,
- Cross-reactivity,
- Interference,
- Precision,
- Carry-over / cross-contamination,
- Multi-center reproducibility, and
- Testing of prospectively collected and banked specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Qiagen GmbH
c/o Melissa Mahall
Director, Regulatory Affairs
1201 Clopper Road
Gaithersburg, MD 20878

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Re: K113319
Trade/Device Name: Rotor-Gene Q MDx
Regulation Number: 21 CFR 862.2570
Regulation Name: Instrumentation for clinical multiplex test systems
Regulatory Class: Class II
Product Code: OOI
Dated: October 21, 2011
Received: Nov. 10, 2011

Dear Ms. Mahall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): k113319

Device Name: **Rotor-Gene® Q MDx**

Sponsor Name: **QIAGEN GmbH**

Indications for Use:

The Rotor-Gene Q MDx instrument with Rotor-Gene Q software version 2.1.0 or higher is a real-time nucleic acid amplification and detection system which measures nucleic acid signals from amplified DNA using fluorescent detection.

The Rotor-Gene Q MDx instrument is intended for *in vitro* diagnostic use with FDA cleared or approved nucleic acid tests in clinical laboratories.

Prescription Use ☒ (21 CFR 801 Subpart D) And/Or Over-The-Counter Use ☐ (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Tamara V. Feddiman

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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